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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,585	12/04/2003	Harry A. Dugger III	11122-040-999	5069
20582	7590	07/14/2004	EXAMINER	
JONES DAY			HAGHIGHATIAN, MINA	
51 Louisiana Aveue, N.W			ART UNIT	
WASHINGTON, DC 20001-2113			PAPER NUMBER	

1616

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/726,585

**Applicant(s)**

DUGGER, HARRY A.

**Examiner**

Mina Haghighatian

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 32-63 and 92-123 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-63 and 92-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 recites the limitation "the flavoring agent" in the composition of claim 32. There is insufficient antecedent basis for this limitation in the claim. This appears to be incorrect dependency error.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32, 36-59, 61-63, 92 and 97-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719,197) in view of Purewal et al (5,605,674).

Kanios teaches compositions and methods for topical administration of pharmaceutically active agents. Topical administration means a direct contact of the formulation with tissue, such as skin or membrane, particularly the oral or buccal mucosa (col. 1, lines 29-59).

Kanios discloses that the composition comprises a therapeutically effective amount of at least one pharmaceutically active agent, a pharmaceutically acceptable solvent for the active agent (col. 2, lines 22-28). The solvent is preferably a polyhydric alcohol such as polypropylene glycol, ethylene glycol, also solvents such as fatty acids such as oleic acid, as well as fatty esters or alcohols. The solvent is present in an amount from about 20 to 50 weight percent based on the total weight of the composition (col. 4, lines 1-49). The concentration of the solubilized active agent can range from 1 and 50% by weight (col. 8, lines 1-9). The acceptable carrier is intended to be any suitable finite or non-finite carrier including liquids, semi-liquids or solid carriers. Thus the active agent may be admixed with carriers such as spray-solution or any non-finite carrier known in the art for delivery of active agents (col. 8, lines 54-67). Other additives may be incorporated into the formulations such as flavorings (col. 10, lines 48-56).

Kanios discloses that pharmaceutically active agents suitable for such formulation include anti-cholinergics, anti-depression agents, agents for treating parkinsons, benzodiazepine antagonists, stimulants, neurotransmitter antagonists, tranquilizers, etc (cols. 12-31).

Kanios lacks specific disclosure on the use of propellants in the spray formulation.

Purewal et al teaches medicinal aerosol formulations which comprise a medicament, a propellant such as 1,1,1,2-tetrafluoroethane and at least one compound having a higher polarity than the said propellant. Purewal, also discloses that aerosol formulations may contain a saturated hydrocarbon propellant, e.g., n-butane, isobutane, pentane and isopentanes (col. 1, lines 60-65). The formulation may also contain the hydrocarbons such as propane, butane isobutane, isopentane, etc, as its high polarity adjuvants (col. 2, lines 19-26).

Puerwal discloses that the aerosol formulations may e delivered to human lung via a metered dose inhaler (col. 2, lines 32-36 and col. 5, lines 1-3). The active agents suitable for the said aerosol formulations are listed in column 5, line 47 to column 6, line 19.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the spray formulations of Kanios by adding a suitable propellant as taught by Purewal with the reasonable expectations of preparing a spray formulation containing propellants which assist in delivery of medicaments to the desired site and ultimately potentiates its absorption.

Claims 33-60 and 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al and Purewal et al, as applied to claims 32, 36-59, 61-63, 92 and 97-123 above, and further in view of Singer et al (5,364,616).

The combined references, discussed above, lack disclosure on the concentration range and examples of the flavoring agents.

Singer teaches methods for prevention or treatment of gingivitis or periodontitis comprising topical administration to oral cavity, a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound, and oral care compositions used thereof. Compositions comprise about 0.001 to about 20% of a H-2 antagonist such as cimetidine, about 2 to about 99% of an oral carrier and about 0.04 to about 2% of flavoring agent by weight. The suitable carriers include ethanol, water and polyhydric alcohols such as glycerin, polyethylene glycol and propylene glycol. Suitable flavoring agents include menthol, oil of wintergreen, oil of peppermint, oil of clove, etc (col. 15-17).

Singer discloses that the said compositions, suitably in the form of a mouthspray, may optionally include other agents such as other active agents such as antibiotics, anti-inflammatories, vitamins and minerals (col. 18-19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings on the spray formulations taught by the combined references, to look in the art for relative and suitable concentration range and examples of the flavoring agent with the reasonable expectations of preparing an oral formulation that is acceptable and tolerable by patients, since flavoring is an important aspect of oral formulations.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/327,195. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123 are generic to all that is recited in claims of copending Application No. 10/327,195. That is, claims of copending Application No. 10/327,195 fall entirely within the scope of claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123. Specifically the formulations containing certain classes of active agents of the copending Application No. 10/327,195 fall within the scope of the formulations of claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123. for example, anti-cholinergics of the instant application fall entirely within the scope of the antiasthmatics of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/726,625. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123 are generic to all that is recited in claims of copending Application No. 10/726,625. That is, claims of copending Application No. 10/726,625 fall entirely within the scope of claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123. Specifically the formulations containing certain classes of active agents of the copending Application No. 10/726,625 fall within the scope of the formulations of claims 32-38, 41, 54, 60-63, 92-100, 103, 116 and 122-123. For example, anti-migraine agents and anesthetics of the instant application fall entirely within the scope of the neurotransmitters of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Mina Haghighatian', with a stylized flourish at the end.

Mina Haghighatian  
Examiner  
Art Unit 1616